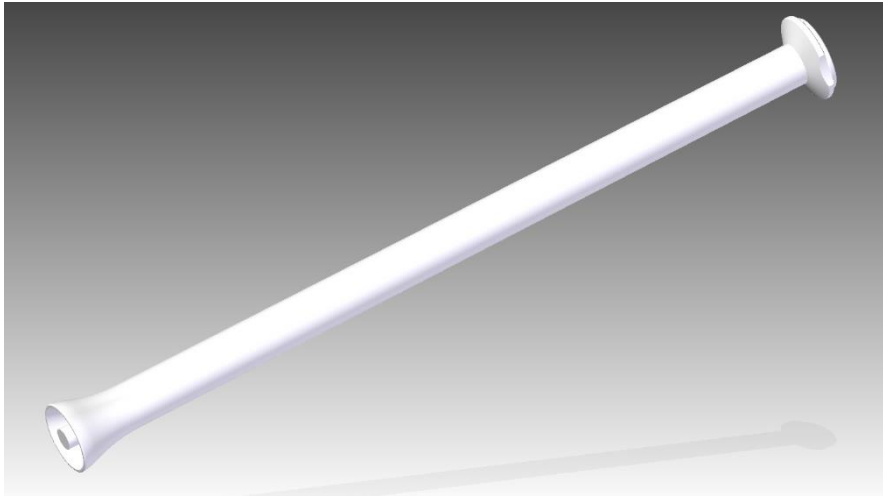


Instruction for use of vaginal-soft-capsule-applicators (art. no. 1022xx)



Manufacturer of vaginal applicator:

Manfred Schägner GmbH
Industriestr. 3
76479 Steinmauern
Germany
phone: +49 7222 9274 0
FAX: + 49 72 22 690 36
e-mail: info@schaegner.de
www.schaegner.de

Please note that following wording of the instruction for use is a suggestion. As Schägner as legal manufacturer of the applicator has no specific information about the medicine/medical device these applicators are packed with, it is up to the pharmaceutical company that encloses the vaginal applicator to the package that contains the vaginal capsule to adapt the instruction for use according to the specific requirements of the pharmaceutical company's vaginal capsule (see also "Demarcation of responsibilities" as stipulated by contract between Schägner and pharmaceutical company).

Suggestion for the instruction for use of vaginal-capsule-applicators:

"The plunger is pulled out of the applicator until it comes to a stop. Then the vaginal capsule is placed firmly into the holder of the applicator by a light twist. The applicator is then introduced into the vagina. This should be best carried out in dorsal position. The vaginal capsule is deposited into the vagina by slowly pressing the applicator plunger until it stops. Finally, the applicator is removed from the vagina.

The vaginal capsule applicator is designed by the manufacturer for single use and should be disposed of as household waste after use.

Note on safety:

- ***Applicators that show obvious damages should not be used but returned to the pharmacy, pharmaceutical company or to the manufacturer."***

Optional reuse of the vaginal soft capsule applicator:

- *the reuseability of the applicator depends on the patient's vaginal flora due to the underlying disease as well as domestic hygienic aspects.*
- *reusing of the applicator is limited to the exhaustion of the medicinal product contained in one package the applicator is packed with*

- *in case the pharmaceutical company designs the applicator to be reused a cleaning procedure as validated by the pharmaceutical company considering the vaginal flora as well as specific bioburden requirements (at least Eur.Pharm.5.1.4 or lower) and accordingly described in the IFU contained in the combination package of applicator and medicinal product has to be performed after each applicator use. The cleaning procedure has to comprise at least:
 - *disassembling of the applicator by withdrawal of the plunger from the tube*
 - *washing of tube and plunger with lukewarm tap-water and mild soap, thorough rinsing of tube and plunger with fresh tap-water, if necessary shaking-off larger amounts of water*
 - *air drying of the applicator parts on a dry and clean surface*
 - *assembling of applicator by inserting the plunger into the tube**

- *Warning: Before each reuse the applicator has to be examined for obvious damages especially at the end which holds the capsule. Applicators that show obvious damages should not be reused but disposed of as household waste.*

Dr. Ute Linder
Manfred Schägner GmbH
Safety manager medical devices

